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INFORMATION DISCLOSURE CITATION

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Atty. Docket No. 0575/48879-A Serial No. 08/763,669-

Applicants

Robert E. Canfield, et al.

Filing Date

December 11, 1996

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Armstrong, et al. 1984. Use of a highly sensitive and specific immunoradiometric assay for detection of human chorionic gonadotropin in urine of normal, nonpregnant and pregnant individuals. J. Clin. Endocrinol. Met. 59:867-874 (Exhibit A)

Barbé, F. et al. 1995. Undetectable luteinizing hormone levels using a monoclonal

immunometric assay. J. Endocrinol Invest. 18(10):806-808 (Exhibit B)

DATE CONSIDERED EXAMINER

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Birken, S., et al. 1993. Structure and significance of human luteinizing hormone-beta core

fragment purified from human pituitary extracts. Endocrinology 133(3):985-989 (Exhibit C)

Blithe, et al. 1988. Purification of β -core fragment from pregnancy urine and demonstration that its carbohydrate moieties differ from those of native human chorionic gonadotropin-β.

Endocrinology 122: 173-180 (Exhibit D)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

malignancies. Cancer Research 48:1361-1366 (Exhibit M)

Pettersson, K. et al. 1991. Monoclonal antibody-based discrepancies between two-site

immunometric tests for lutropin. Clin. Chem. 37(10:Pt. 1): 1745-1748.(Exhibit N)

Prentice, L.G. and Ryan, R.J. 1975. LH and its subunits in human pituitary, serum and urine

Clin Endocrinol Metab 40:2 303-312-(Exhibit O)

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*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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